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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,489	11/14/2003	Hau H. Duong	A-65682-2/RMS/RMK/JML/463	1026

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,489	DUONG ET AL.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/9/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-25* is/are pending in the application.

4a) Of the above claim(s) *14-16 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13,17,18 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of species (1) (claim 13) and species (4) (claim 18), in the reply filed on June 13, 2006 is acknowledged. Therefore, claims 11-13, 17, 18, and 20-25 will be examined.

Specification

2. The disclosure is objected to because of the following informalities: (1) since US Application No. 09/397,957 now is US Patent No. 6,740,518, applicant is required to update this information in the first sentence of the specification; (2) there are Figures 6A-1 to 6A-4 and 6B-1 to 6B-4. However, BRIEF DESCRIPTION OF THE DRAWINGS of the specification only describes Figures 6A and 6B; and (3) there are Figures 10A to 10D. However, BRIEF DESCRIPTION OF THE DRAWINGS of the specification only describes Figure 10.

Appropriate correction is required.

Claim Objections

3. Claims 12, 13, 17, 18, and 20-24 are objected to because of the following informality: "A method" in the claims should be "The method".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. New Matter

Claims 13 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claims 13 and 20 have been added to this application. However, pages 101-110 of the specification as indicated by applicant in applicant's remarks filed on April 9, 2004 fail to define or provide any disclosure to support the phrase "applying the output waveform to a digital lock-in amplifier" recited in claim 13 and the phrase "the input waveform comprises at least a portion having a frequency of about 100 kHz" recited in claim 20.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application."

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11-13, 17, 18, and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 11 or 25 is rejected as vague and indefinite. Although claim 11 or 25 is directed to a method for detecting the presence of target analytes, there is no method step for detecting the presence of target analytes and the goal of the claim cannot be reached. Please clarify.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 11-13, 17, 18, 20, 21, 24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Meade (US Patent No. 6,013,459, filed on June 12, 1997).

Regarding claims 11 and 24, Meade teaches providing an electrode comprising a self assembled monolayer (see column 17, lines 23-42) and an assay complex covalently attached to the electrode, the assay complex comprising a target analyte, a capture binding ligand and an electron transfer moiety (see column 1, lines 41-55, column 2, lines 4-10 and claim 1 in columns 24 and 25), applying an input waveform to the electrode, the input waveform illiciting a response of characteristic waveform from the electrode indicative of electron transfer between the electron transfer moiety and the electrode, receiving an output waveform from the electrode, responsive

to the input waveform; analyzing the output waveform for the presence of the characteristic waveform as recited in claim 11 and predicting the characteristic waveform based at least on the electron transfer moiety as recited in claim 24 (see column 1, lines 41-55 and columns 21-24).

Regarding claim 12, Meade teaches that the act of analyzing the output waveform includes utilizing chronocoulometry (see column 20, lines 27-44).

Regarding claim 13, Meade teaches that the act of analyzing the output waveform for presence of the characteristic waveform includes applying the output waveform to a digital lock-in amplifier (see column 20, lines 26-44 and column 21, lines 22-33).

Regarding claim 17, Meade teaches that the electron transfer moiety comprises a transition metal complex (see claim 1 in columns 24 and 25).

Regarding claim 18, Meade teaches that the target analyte comprises a nucleic acid (claims 1, 22, and 23 in columns 24 and 25).

Regarding claim 20, Meade teaches that the input waveform comprises at least a portion having a frequency of about 100 kHz (see column 21, lines 55-67 and column 22, lines 1-5).

Regarding claim 21, Meade teaches that the input waveform is a voltage waveform and the output waveform is a current waveform (see claims 11 and 13 in column 25).

Regarding claim 25, Meade teaches providing an electrode comprising a self-assembled monolayer (see column 17, lines 23-42) and an assay complex covalently attached to the electrode, the assay complex comprising a target analyte, a capture binding ligand and an electron transfer moiety (see column 1, lines 41-55, column 2, lines 4-10 and claim 1 in columns 24 and 25); applying an input waveform to the electrode; receiving an output waveform from the electrode, responsive to the input waveform; analyzing the output waveform using

chronocoulometry to identify electron transfer between the electron transfer moiety and the electrode (see column 1, lines 41-55, column 20, lines 27-44, and columns 21-24).

Therefore, Meade teaches all limitations recited in claims 11-13, 17, 18, 20, 21, 24, and 25.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meade as applied to claims 11-13, 17, 18, 20, 21, 24, and 25 above, and further in view of Mihara *et al.*, (US Patent No. 5,487,032, published on January 23, 1996).

The teachings of Meade have been summarized previously, *supra*.

Meade does not disclose that the characteristic waveform comprises a Gaussian waveform as recited in claim 22.

Mihara *et al.,* teach to apply a Gaussian waveform to an electrode (see column 3, lines 13-16 and Figure 4).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 22 wherein the characteristic waveform comprises a Gaussian waveform in view of the prior art of Meade and Mihara *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of input waveform (ie., the input waveform taught by Meade) from another kind of input waveform (ie., Gaussian waveform taught by Mihara *et al.,*) during the process of performing the method recited in claim 22 or 23, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the input waveform taught by Meade and Gaussian waveform taught by Mihara *et al.*, are used for the same purpose (ie., serving as an input signal).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

13. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meade in view of Mihara *et al.,* as applied to claims 11-13, 17, 18, 20-22, 24, and 25 above.

The teachings of Meade and Mihara *et al.,* have been summarized previously, *supra.*

Meade and Mihara *et al.,* do not disclose that the characteristic waveform comprises a modified Gaussian waveform as recited in claim 23.

However, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 23 wherein the characteristic waveform comprises a modified Gaussian waveform in view of the prior art of Meade and Mihara *et al.*. One having ordinary skill in the art has been motivated to do so because optimization of the intensity of Gaussian waveform, in the absence of convincing evidence to the contrary, would have been obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to modify the intensity of Gaussian waveform. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive, in the absence of an unexpected result, to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05).

Conclusion

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

August 21, 2006

FRANK LU
PRIMARY EXAMINER